

Remarks

Claims 18, 19, and 22-84 will be pending upon entry of this amendment. Claims 1 - 17 and 20-21 have been canceled without prejudice or disclaimer. New claims 22-84 have been added so as to claim additional embodiments of the elected group. Support is found throughout the specification as originally filed. No new matter has been introduced.

Claims 18 and 19 have been amended so as to refer to the elected polynucleotide. No new matter has been added to the claims by way of amendment. Claims 18-19 have been withdrawn by the Examiner as directed to a nonelected group.

The title has been amended to be more descriptive of the claimed subject matter, as requested by the Examiner. The amendment is supported *inter alia* by Table 1. Thus, no new matter is introduced by this amendment.

The specification has also been amended to replace the sequence listing with a substitute sequence listing and to add appropriate sequence identifiers to the text.

I. The Sequence Listing

The previous sequence listing in this case was found not to comply with 37 C.F.R. 1.821-1.825 because certain peptide sequences were not included in the sequence listing and identified with a sequence identifier in the specification. This amendment rectifies this deficiency by requesting that the sequence listing from related application Ser. No. 09/765,272 be used. Amendments to the specification have introduced the required sequence identifiers. Thus, it is assumed that the sequence disclosure requirements have now been met, and that the objection will be withdrawn.

II. The Restriction Requirement

Applicants' election with traversal of the claims of Group I as directed to SEQ ID NOS:55 and 56 has been made final. Applicants note, however, that claims 18 and 19 are directed to methods of detecting *Streptococcus*, formerly classified by the Examiner as Group V. Since the polynucleotides of Group I and the methods of Group V related as between a product and a process for using the product, and the process claims include all the limitations of the product, the Examiner in any case would be obligated to rejoin the method claims if the elected product claims are found allowable. In light of the decisions in *In re*

Ochiai, 71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995) and *In re Brouwer*, 77 F.3d 422, 37 USPQ2d 1663 (Fed. Cir. 1996), a notice was published in the Official Gazette which set forth new guidelines for the treatment of product and process claims. See 1184 OG 86 (March 26, 1996). Specifically, the notice states that "in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim depends from or otherwise includes all the limitations of an allowed product claim." *Id.* Accordingly, Applicants respectfully request that if any of the claims of Group I are found allowable, the process claims of Group V be rejoined and examined for patentability.

III. The Written Description Rejection

Claims 1-9 and 13 are rejected as allegedly lacking written description. The rejection as it applies to newly submitted claims 22-84 is respectfully traversed.

Initially, it is noted that the concerns regarding claim 2 which are expressed in Paper No. 10 at page 6, line 12, through page 7, line 3 have been obviated by the cancelation of claim 2.

The Examiner is concerned that the claims as previously presented, due to use of the word "comprising" in several of the claims, would read on undisclosed flanking sequences or sequences of undisclosed genes. Applicants disagree. However, the newly added claims recite "consisting of" with respect to the claimed sequences, which Applicants believe would alleviate the Examiner's concern and overcome the rejection. Thus, the withdrawal of this rejection is respectfully requested.

IV. The Enablement Rejections

A. Claims 1-9 and 13

Claims 1-9 and 13 are rejected as allegedly lacking enablement. This rejection as it applies to newly submitted claims 22-84 is respectfully traversed.

The Examiner's concerns regarding enablement are based in part on the same objections expressed in the written description rejection, *i.e.*, that the claims capture undescribed sequences. For example, the Examiner states:

Applicant's specification (page 5, lines 17-37) sets forth that the polynucleotide of the invention can be used diagnostically. However, such a detection is limited to consisting of SEQ ID NO:55 or specific fragments thereof, since the addition of an indefinite number of nucleotides 3' and 5' to

SEQ ID NO:55 would unpredictably effect the ability to use SEQ ID NO:55 in a well established manner. Applicant's have not demonstrated that large sequences comprising SEQ ID NO:55 have this ability.

Paper No. 10 at page 8, last paragraph, through page 9, line 3. Applicants maintain that the newly added claims do not recite any undescribed sequences, as discussed above. Furthermore, the claimed polynucleotides can be used not only for the detection of *Streptococci*, but also as antigens for vaccines. For example, the specification at page 9 states that the disclosed nucleic acid sequences were selected because they encode potentially immunogenic peptides. The specification then goes on to describe the selection of the immunogenic polypeptides at page 9, last paragraph, through page 11, first whole paragraph. The sequences were identified by analysis which included use of an algorithm, the presence of certain signal sequences, the presence of a consensus sequence for lipoprotein cleavage, and the presence of a consensus sequence for surface anchoring in gram-positive bacteria. Thus, not only the polynucleotide of SEQ ID NO:55 and fragments thereof, but also the claimed variant sequences are enabled by the disclosure, because the variants can be used as immunogens in a vaccine in the same manner as SEQ ID NO:55.

Moreover, the Examiner is concerned by the absence of typical start and stop codons in SEQ ID NO:55, which would denote a full length open reading frame. The specification teaches clearly that "[t]he selected ORFs do not consist of complete ORFs." Specification at page 9, line 22. The specification explains further in the same paragraph that portions of the complete ORFs have been deliberately omitted in order to simplify production of the recombinant protein, for example, by removing highly hydrophobic sequences. Thus, the selected ORFs are not complete because they have been modified to improve their use as antigens. Furthermore, the specification discloses that a more complete listing of the *S. pneumoniae* genome can be found in copending application Ser. No. 60/029,960, filed October 31, 1996. Specification at page 9, lines 16-19. The ordinary skilled artisan would have no difficulty identifying the complete ORF in the copending application based on the disclosure of SEQ ID NO:55 in the instant application. Copending application Ser. No. 60/029,960 has been incorporated by reference in the instant specification. See specification at page 9, lines 18-19.

Thus, Applicants assert that the claims are enabled as to their entire scope and respectfully request the withdrawal of this rejection.

B. Claim 9

This claim is rejected as lacking enablement because it recites polynucleotides complementary to SEQ ID NO:55 which do not encode the polypeptide of SEQ ID NO:56. The newly added claims do not recite polynucleotides complementary to SEQ ID NO:55 in vectors or recombinant cells or used in expressing polypeptides. Therefore, as the rejection pertains to the new claims, Applicants respectfully traverse the rejection and request its withdrawal.

V. The Indefiniteness Rejection

Claims 1-9 and 13 are rejected as allegedly indefinite for the inclusion of nonelected subject matter. Claims 1-9 and 13 have been cancelled. As the rejection pertains to the new claims, Applicants respectfully traverse the rejection and request its withdrawal.

VI. Rejection Under 35 U.S.C. 102(b)

Claim 2 is rejected as allegedly anticipated by Birkett et al. or Boehringer Mannheim 1991 Catalog or Stratagene 1991 Catalog. The cited references allegedly inherently disclose six consecutive nucleotides that would hybridize under stringent conditions with SEQ ID NO:55 or its complement. The rejection is respectfully traversed.

Claim 2 has been cancelled. New claim 55, which is directed to polynucleotides which hybridizes with either SEQ ID NO:55 or its full complement, requires hybridization to at least about 15 nucleotides. Support for this requirement is found in the specification at page 14, lines 1-3. Thus, the claims are not anticipated by the cited references. Withdrawal of the rejection is respectfully requested.

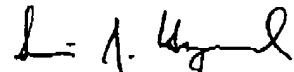
Conclusion

In view of the foregoing remarks, Applicants believe that this application is now in condition for allowance. An early notice to that effect is urged. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicant would expedite the examination of this application.

Finally, if there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

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